

RULEMAKING NOTICE FORM

Notice Number _____	Rule Number _____	Ph 900
1. Agency Name & Address: N. H. Board of Pharmacy 57 Regional Drive Concord, NH 03301-8518	2. RSA Authority: RSA 318:5-a, I, IV-a, and V; and RSA 318:37, II	
	3. Federal Authority: N/A	
	4. Type of Action:	
	Adoption _____	
	Amendment _____	
	Repeal _____	
	Readoption _____	
	Readoption w/amendment _____	XXX

5. Short Title: **MAIL-ORDER PHARMACIES**

6. (a) Summary of what the rule says and the effect of the rule on those regulated:

This chapter describes the original and renewal application processes and the criteria for the issuance of a registration as a mail-order pharmacy. The rules also impose on-going requirements for registered mail-order pharmacies. Finally, the rules specify the reasons for revocation of a mail-order pharmacy registration.

The changes to the rules include but are not limited to: amending definitions to reflect statutory wording; requiring more detailed information about applicants for both initial and renewal registrations; raising the fee for an initial registration to \$300 and for a renewal registration to \$250; clarifying reasons for refusal/revocation of a registration; imposing a late fee for late renewals; and setting requirements and prohibitions relative to dispensing, adulteration, misbranding, shipping and packaging.

The full text of the proposed rules can be viewed on the Board's website:

<http://www.nh.gov/pharmacy/rulemaking.htm>

6. (b) Brief description of the groups affected:

Any person or entity operating a pharmacy located outside New Hampshire but within the U.S. seeking to dispense prescription drugs or devices under a prescription drug order and deliver the drug or device to the patient in New Hampshire will be affected by these rules.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

Rule	Statute Implemented
Ph 901	RSA 541-A:8
Ph 902	RSA 541-A:7 and RSA 541-A:8
Ph 903 – Ph 907	RSA 318:37

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name:	Paul Boisseau, R.Ph.	Title:	Executive Director
Address:	N. H. Board of Pharmacy 57 Regional Drive Concord, NH 03301-8518	Phone #:	271-7842
		Fax#:	271-2856
		E-mail:	paul.boisseau@nh.gov

TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **At the close of the Board's Public Comment Hearing on April 16, 2008.**

☒ Fax ☒ E-mail ☐ Other format (specify): **N/A**

8. Public hearing scheduled for:

Date and Time: **10 am – 12 noon, Wednesday, April 16, 2008**

Place: **Board of Pharmacy Conference Room
57 Regional Drive
Concord, NH 03301-8518**

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

Fiscal Impact Statement for New Hampshire Board of Pharmacy rules governing Mail-Order Pharmacies. [Ph 900]

1. Comparison of the costs of the proposed rule(s) to the existing rule(s):

When compared to the existing rules, the proposed rules will increase state general fund revenue by approximately \$36,000 annually, and increase costs to independently businesses by an indeterminable amount to the extent they seek registration as a mail-order pharmacy.

2. Cite the Federal mandate. Identify the impact on state funds:

No federal mandate, no impact on state funds.

3. Cost and benefits of the proposed rule(s):

A. To State general or State special funds:

The proposed rules would increase the fee charged to mail-order pharmacies for initial registration from \$150 to \$300, increase the renewal registration fee from \$150 to \$250, and add a \$25 late fee for submission of renewal applications after March 31. Assuming the number of applicants for initial and renewal mail-order registrations remains the same, the Board estimates these fee changes will increase state general fund revenue by approximately \$36,000 annually.

B. To State citizens and political subdivisions:

None.

C. To independently owned businesses:

The Board states the costs to independently owned businesses of completing an application for initial registration may increase by an indeterminable amount due to such applicants being required to provide information or documents that are not required under the existing rule. To the extent they are required to pay fees as stated in A. above, they will also experience increased costs.

FIS # 08:034 , dated 02/29/2008

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposed rules do not violate Part I, Article 28-a of the New Hampshire Constitution because they do not mandate or assign any program or responsibilities to any political subdivision.

Readopt with amendment Ph 900, effective 4-5-01 (Doc. #7474), to read as follows:

CHAPTER Ph 900 MAIL-ORDER PHARMACY

Statutory Authority: RSA 318:37, II

PART Ph ~~901 PURPOSE AND~~901 SCOPE

Ph 901.~~01 Purpose and~~01 Scope. The provisions of this chapter shall apply to, and impose duties upon, all mail-order pharmacies holding registrations issued by the board.

PART Ph 902 DEFINITIONS

Ph 902.~~01 Definitions. Except where the context makes another meaning manifest, the following definitions shall apply:~~

~~—(a) 01 “Mail-order pharmacy” means any “mail-order pharmacy” as defined in RSA 318:1, VII-a-b, namely, “a pharmacy that is located outside in a state of New Hampshire that sells, ships, mails, or delivers, in any manner, prescription drugs or devices at retail into New Hampshire. the United States, other than this state, whose primary business is to dispense a prescription drug or device under a prescription drug order and to deliver the drug or device to a patient, including a patient in this state, by the United States mail, a common carrier, or a delivery service. Mail-order pharmacies include, but are not limited to, pharmacies that do business via the Internet or other electronic media.”~~

PART Ph 903 REGISTRATION

Ph 903.01 Application.

(a) No person shall conduct or operate a mail-order pharmacy located outside of this state by ~~shipping, mailing, or~~ delivering in any manner prescription drugs or prescription devices into this state unless such pharmacy is registered in New Hampshire and a permit has been issued by the New Hampshire board of pharmacy.

(b) Application form MO-1 ~~for registration, “Registration of mail-order pharmacies-Mail-order Pharmacy,”~~ may be obtained from and shall be filed at the office of the board, identified in Ph 103.03.

(c) Applicants for registration as a mail-order pharmacy shall submit ~~an application a~~ completed MO-1 that contains the following information:

(1) Name, address, telephone number and Internet address, if applicable, of the pharmacy;

(2) The names, addresses and titles, of all principal corporate officers, if incorporated, and if unincorporated, partners, or ~~owner~~ owners of the pharmacy;

~~(3) The name~~

(3) If a corporation, a certificate of incorporation from the state in which incorporated;

(4) If a limited liability company, partnership or sole proprietorship, a tax ID number;

(5) The name and state license number of the pharmacist-in-charge of the location listed in (1) above;

~~(4) The name and address of a resident agent in New Hampshire for service of process;~~

~~(5)~~

(6) A copy of the pharmacy's current license, permit, or registration certificate issued used by the regulatory or licensing agency of the state in which the pharmacy is located, as well as a copy of the current DEA registration, if applicable;

~~(6)~~

(7) A copy of the most recent inspection report conducted by the state in which the pharmacy is located;

(8) A list of any and all Internet links from which the mail-order pharmacy solicits business; and

(9) Signature of the pharmacist-in-charge and date; and

(d) As attachments to the completed MO-1, the applicant shall provide the following:

(1) At least 2 photographs of the actual existing exterior, include the pharmacy signage, of the building in which the pharmacy will be or is currently located;

(2) At least 2 photographs of the prescription department as viewed by an approaching patron;

(3) At least 4 photographs of the prescription department as viewed from the interior, showing the prescription compounding area, refrigerator, water facilities and pharmaceutical inventory storage area;

(4) A physical description and floor plan of the pharmacy and drug storage areas;

(5) A prescription label, containing the name, address and phone number of the pharmacy, that would be used on finished prescription products mailed to NH residents;

(6) A sample copy of a printed patient medication profile that shall include the following information:

- a. Name and address of the patient;
- b. Name, address and DEA registration number of the prescriber;
- c. Name, strength and quantity of drug dispensed;
- d. Assigned prescription number;
- e. Date of original filling; and
- f. Date of refill(s); and

(7) The prescribed fee which shall be \$~~150~~ 300.

~~(d)~~

(e) Any person or ~~mail-order pharmacy who provides services, as defined in Ph 902.01(a),~~ pharmacy whose pharmacy business fits the definition of a mail-order pharmacy and delivers prescription drugs or prescription devices to New Hampshire residents from more than one out-of-state pharmacy shall register each such pharmacy separately.

PART Ph 904 REGISTRATIONS – CHANGES IN SUPPORTING DATA

Ph 904.01 Reporting Changes.

(a) The mail-order pharmacy to which a registration has been issued shall, within 30-days of any change of information supplied in the original application, notify the board.

(b) The notice required pursuant to (a) above shall contain:

- (1) Current New Hampshire registration number of the pharmacy;
- (2) Name of the pharmacy, old and new, if applicable;
- (3) Address of the pharmacy, old and new, if applicable;
- (4) Name of the pharmacist-in-charge, old and new, if applicable; ~~and~~
- (5) Name(s), addresses and titles, of new corporate officers, or partners, or owners.

(c) A new registration shall be required for a change of ownership of an established pharmacy to a successor business entity which results in a change in the controlling interest in the pharmacy.

PART Ph 905 REVOCATION AND DENIAL

Ph 905.01 Effect of Revocation and Denial.

(a) The board shall refuse to issue a registration or shall, after notice and opportunity for a hearing, revoke a registration whenever the board finds out that a mail-order pharmacy, its pharmacist-in-charge, owner(s) or corporate officer(s) has:

(1) Made a materially false representations or withheld material information in connection with obtaining its registration;

(2) Been found guilty of ~~or plead guilty or nolo contendere to~~ any felony in connection with the practice of pharmacy or ~~the~~ distribution of drugs;

(3) Made false representations in connection with the practice of pharmacy that endanger or are likely to endanger the health or safety of the public, or that defraud any person;

(4) Failed to comply with RSA 318:37, II ~~and/or~~, the provisions of Ph 900 ~~of the New Hampshire Code of Administrative Rules; or, or both;~~

~~(5) Been the subject of a negligence~~

(5) Based on an investigation of a complaint resulting from the dispensing of prescription drugs or prescription devices to a resident of New Hampshire ~~and based on an investigation of such complaint~~ been found to be negligent:

a. By the board of pharmacy of the state in which the pharmacy is located; or

b. By the New Hampshire board of pharmacy if the board of pharmacy of the state where the pharmacy is located failed to initiate an investigation of such complaint within 45 days after referral of the complaint from the New Hampshire board of pharmacy; or

(6) Been found guilty of any violation of federal, state or local drug law or have entered into any agreement to resolve violations of such.

(b) A mail-order pharmacy shall notify the board within 5 days of ~~receipt of~~ any order or decision by a board of pharmacy, or any other state or federal agency, imposing disciplinary action on the pharmacy. Notwithstanding the provisions of paragraph (a) above, if the license, permit or registration in the state where the pharmacy is located, is suspended or revoked, then the pharmacy's

registration in New Hampshire shall, after notice and opportunity for hearing, ~~shall be immediately suspended or~~ revoked for the same period of time.

PART Ph 906- RENEWAL OF REGISTRATIONS

Ph 906.01 Renewal Registrations Required. All mail-order pharmacy registrations shall expire annually on March 31.

Ph 906.02 Renewal Application Where Obtained and Filed. Applications for the renewal of a registration for a mail-order pharmacy may be obtained from, and shall be filed at ~~the~~ that office of the board, identified in Ph 103.03.

Ph 906.03 Renewal Application Contents and When Filed. Renewal applications shall be filed with the board in accordance with the following:

(a) Applications for renewal of a registration for a mail-order pharmacy shall be made on form MO-2: “Application for Renewal of Registration for Mail-order Pharmacy;”

(b) Each applicant shall provide the following on or as an attachment to form MO-2 no later than March 31:

(1) Name, address, telephone number and Internet address, if applicable, of the pharmacy;

(2) The name of the pharmacist-in-charge;

~~(3) Any ownership changes that have not been reported according to the provisions of Ph 903.01; and~~

~~(4) Signature of the pharmacist in charge and date.~~

~~(e)~~

(3) The names, addresses and titles, of all principal corporate officers if incorporated, or all partners or owners of the pharmacy if not incorporated; and

(4) A copy of the current license, permit, or registration certificate ~~issued~~ used by the regulatory or licensing agency of the state in which the pharmacy is located, as well as a copy of the current DEA registration, if applicable, shall be submitted with the renewal application;

~~(d)~~

(5) The application and the prescribed fee of \$150 shall be filed with the board no later than March 31, 2010; and

(6) Signature of the pharmacist-in-charge and date.

(c) Renewal applications received after March 31 shall be subject to a \$25 administrative late fee and no registration shall be issued until all fees are paid in full.

PART Ph 907 CONDITIONS OF REGISTRATION

Ph 907.01 Compliance. As conditions of registration, the mail-order pharmacy shall ~~comply with the following~~:

(a) Maintain at all times a valid unexpired permit, license, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident;

(b) Maintain in readily retrievable form, records of legend drugs ~~and/or~~ devices, or both dispensed to New Hampshire patients;

(c) Supply upon request, any and all information needed by the board to carry out its responsibilities under the statutes and rules pertaining to mail-order pharmacies;

(d) Provide for a toll-free telephone communication consultation between New Hampshire patients and a pharmacist at the mail-order pharmacy who has access to the patient's records, and ensure that said such toll-free telephone number(s) ~~will~~ shall be placed upon the label affixed to each prescription container; ~~and~~

(e) Provide to the board, upon request, with a copy of the policies and procedures governing:

(1) Normal delivery protocols and times;

(2) Any special packaging or procedures used in delivering temperature-sensitive drug products;

(3) The procedure to be followed if the patient's medication is not available at the mail-order pharmacy, or if delivery will be delayed beyond the normal delivery time;

(4) The procedure to be followed upon receipt of a prescription for an acute illness, which shall include a procedure for delivery of the medication to the patient from the mail-order pharmacy at the earliest possible time, such as courier delivery, or an alternative that assures the patient the opportunity to obtain the medication at the earliest possible time; and

(5) The procedure to be followed when the mail-order pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mail prescription drugs become available.

(f) All finished prescription products shipped to New Hampshire residents shall be packaged in tamper-evident containers;

(g) A mail-order pharmacy shall not dispense or sell to the public, any drug which is adulterated or misbranded.

(h) A mail-order pharmacy shall supply, upon request from the board, a statement of origin of any specific drug dispensed to a New Hampshire resident;

(i) A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that:

(1) The order for such a drug was issued on the basis of an Internet medical history form, an Internet based consultation or telephonic consultation, without a preexisting patient practitioner relationship;

(2) The order has been issued for a non-legitimate medical purpose; or

(3) The order was not written by an authorized practitioner.

(j) Any mail-order pharmacy shipping finished prescription products into the State of New Hampshire shall use the address on file with the New Hampshire Board of Pharmacy as the return address on the labels of any package shipped into the State of New Hampshire. The return address shall be placed on the package in a clear and prominent manner.

APPENDIX**CROSS-REFERENCE TABLE**

Rule	Statute Implemented
Ph 901	RSA 541-A:8
Ph 902	RSA 541-A:7 and RSA 541-A:8
Ph 903 – Ph 907	RSA 318:37